

# **EXHIBIT II**

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ETHICON, INC.

a Johnson & Johnson company

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TEN YEAR IN VIVO SUTURE STUDY  
SCANNING ELECTRON MICROSCOPY  
FIVE YEAR REPORT

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Introduction

Twenty-four Beagle dogs had been implanted in November 1985 with sets of ETHILON™, PVDF, PROLENE™ and Novafil 5-0 sutures subcutaneously in the fascia of the lateral dorsal thorax. Five years later, in June and July of 1990, five dogs were euthanatized and the suture implants removed. The explants were received in the microscopy department in weekly intervals.

Experimental

One set of sutures from 5 dogs (#1994, 2000, 2006, 2012, 2018), six sites per dog, was received in sterile water in plastic vials. In some cases a short length of the suture was above the water surface and this segment was discarded. The wet total length of each of the sutures was placed on a micro slide with water from the vial to keep the suture wet. The sample was covered with a cover slip and then examined in the Zeiss compound optical microscope at 110x magnification under crossed polars. Photomicrographs of areas of interest however, were not prepared under crossed polars but in ordinary transmitted light. Current instrumentation does not provide for low light level photomicroscopy, which meant a loss of some of the observations made under crossed polars. (SEM photomicrographs were used instead to show these findings.)

Segments of the wet sutures which showed areas of interest were then air dried overnight and divided in half. One half was examined in its dry state under crossed polars in the Zeiss light microscope. Photomicrographs were prepared in ordinary transmitted light at 110x magnification. The other half was mounted on a carbon stub with copper tape and sputter-coated with gold under vacuum to provide an electron conductive surface. These suture segments were then examined in the JEOL JSM 840 AII SEM. Photomicrographs were taken at 500x magnification.

FEB 19 1993

RD-CENTRAL FILE

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### Results and Discussion

Results of light microscopy in the wet and dry state will not be discussed here in detail. A table is included in this report which summarizes the light microscopical (LM) observations. It can be said unequivocally that the cracking that was seen in any of the sutures was not introduced by sample preparation, i.e., drying. If cracking was observed on a dry suture in the light microscope or in the SEM, the same cracking was also found on the same suture after it had been in body fluids and then in sterile water, without ever having dried.

#### SEM of ETHILON Explants: Figure 1, 2

Suture explants from all five dogs from all sites showed cracking and abrasions in at least 30% of the total suture surface. The abrasions were deep enough to loosen the dyed surface layer of several microns. The cracking shown was found in the undyed underlying layer.

#### SEM of PVDF Explants: Figure 3, 4

No cracking or abrasions were found in any of the explants. A few longitudinal score marks and some mechanical damage, probably not due to degradation, were observed.

#### SEM of PROLENE Explants: Figure 5, 6

Explanted sutures from dogs 1994, 2000 and 2006 did not show any cracking or abrasions. On explants from dogs 2012 and 2018 a few cracked areas were observed; both of these sutures came from site 4.

#### SEM of Novafil Explants: Figure 7, 8, 9

None of the transverse cracking as seen in PROLENE and ETHILON was found on these sutures. Longitudinal cracks with suture material peeling away from it were found on most of the explants. Mechanical damage, probably not due to degradation, was also observed in one case. However, when the oldest explant was reexamined after it had been in sterile water for 45 days, small transverse cracks were found in one area.

### Conclusions

After 5 years *in vivo* the PVDF 5-0 suture was the only explanted material from five dogs which did not show any surface damage due to degradation. Out of seven PROLENE explants, two revealed cracking. All ETHILON explants were heavily cracked and abraded down to the undyed underlying layer. The Novafil explants exhibited longitudinal cracks and in one 45 day old explanted suture some transverse cracking was observed.

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These results may be compared with those of the two year study. (Memo by Frank Schiller 8-26-87.) ETHILON had shown cracking at the two year point; at five years the cracked surface was abraded down to the underlying undyed layer. The PROLENE surface, intact at the two year point, showed signs of degradation at five years. The only intact surface after five years was that of all the PVDF explants. Novafil results seemed to be more ambiguous.

*E. Lindemann*

E. Lindemann

DOG.EL  
Attachment

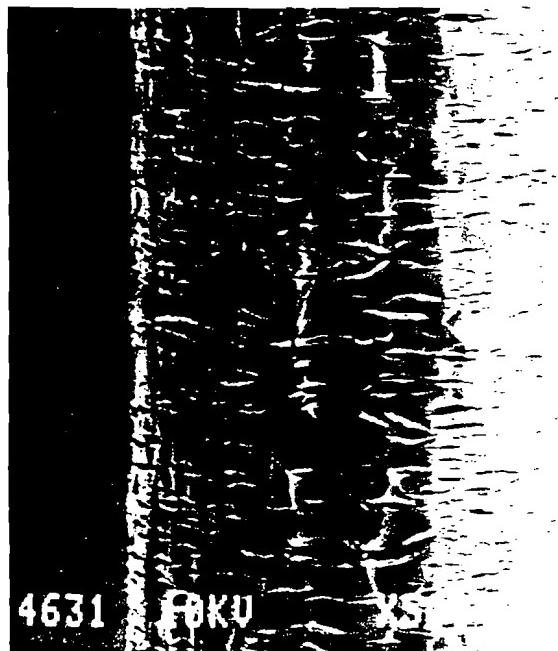
## LM Observations on Explanted Sutures after 5 Years in Dogs

SR #	Suture	Dog	Site	LM H <sub>2</sub> O	LM dry	Photo #
30691	PROLENE	1994	1	No Damage	No Damage	2280, 2336
	PVDF		2	No Damage	No Damage	2281, 2337
	ETHILON		3	Damage	Damage	2282, 2338
	Novafil		4	No Damage	No Damage	2283, 2339
	PROLENE		5	No Damage	Damage	2284, 2340
	ETHILON		6	Damage	Damage	2285, 2341
30702	Novafil	2000	1	No Damage	No Damage	2286, 2300
	PROLENE		2	No Damage	No Damage	2287, 2301
	PVDF		3	No Damage	No Damage	2288, 2302
	ETHILON		4	Damage	Damage	2289, 2303
	Novafil		5	No Damage	No Damage	2290, 2304
	PROLENE		6	No Damage	No Damage	2291, 2305
30716	ETHILON	2006	1	Damage	Damage	2294, 2306
	PVDF		2	No Damage	No Damage	2295, 2307
	PROLENE		3	No Damage	No Damage	2296, 2308
	Novafil		4	No Damage	No Damage	2297, 2309
	PVDF		5	No Damage	No Damage	2298, 2310
	Novafil		6	No Damage	No Damage	2299, 2311
30725	PVDF	2012	1	No Damage	No Damage	2312, 2318
	ETHILON		2	Damage	Damage	2313, 2319
	Novafil		3	No Damage	No Damage	2314, 2320
	PROLENE		4	Cracking	Cracking	2315, 2321
	ETHILON		5	Damage	Damage	2316, 2322
	PVDF		6	No Damage	No Damage	2317, 2323
30785	ETHILON	2018	1	Damage	Damage	2324, 2330
	Novafil		2	No Damage	No Damage	2325, 2331
	ETHILON		3	Damage	Damage	2326, 2332
	PROLENE		4	Cracking	Cracking	2327, 2333
	PVDF		5	No Damage	No Damage	2328, 2334
	Novafil		6	No Damage	No Damage	2329, 2335

DOG.EL/2

Figure 1

Ethilon Explants



4631

20KU

Dog #1994 Site 3

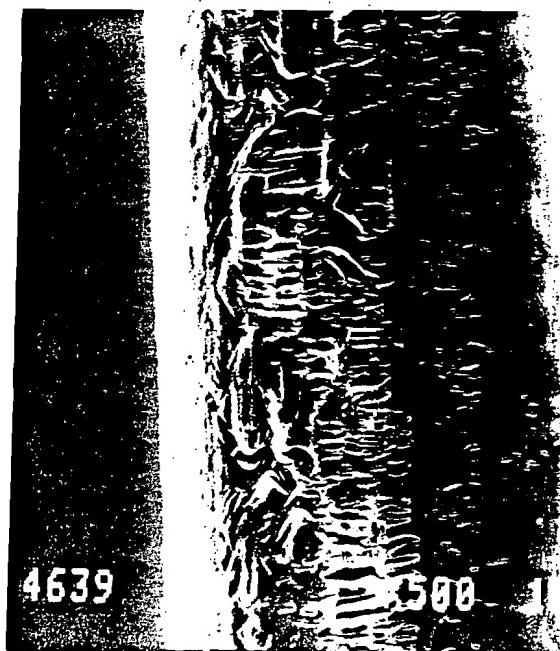
WD15 4635

20KU

X500

WD1

Dog #1994 Site 6



4639

500

Dog #2000 Site 4

15

4634

20KU

X500

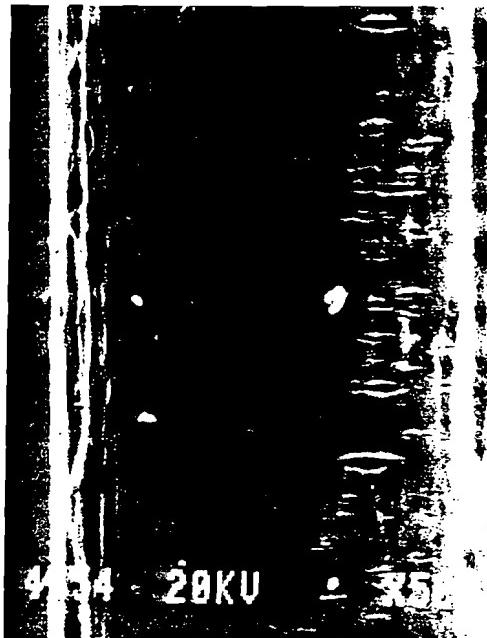
0.1μm WD1

Dog #2006 Site 1

ETH.MESH.11336169

Figure 2

Ethilon Explants



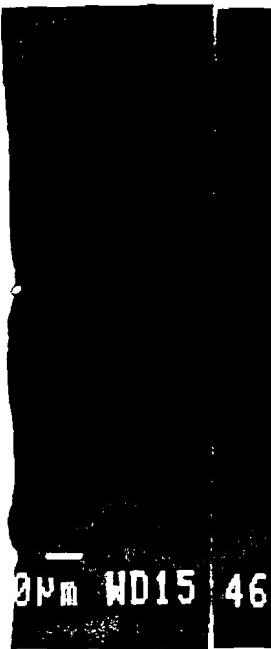
Dog #2012 Site 2



Dog #2012 Site 5



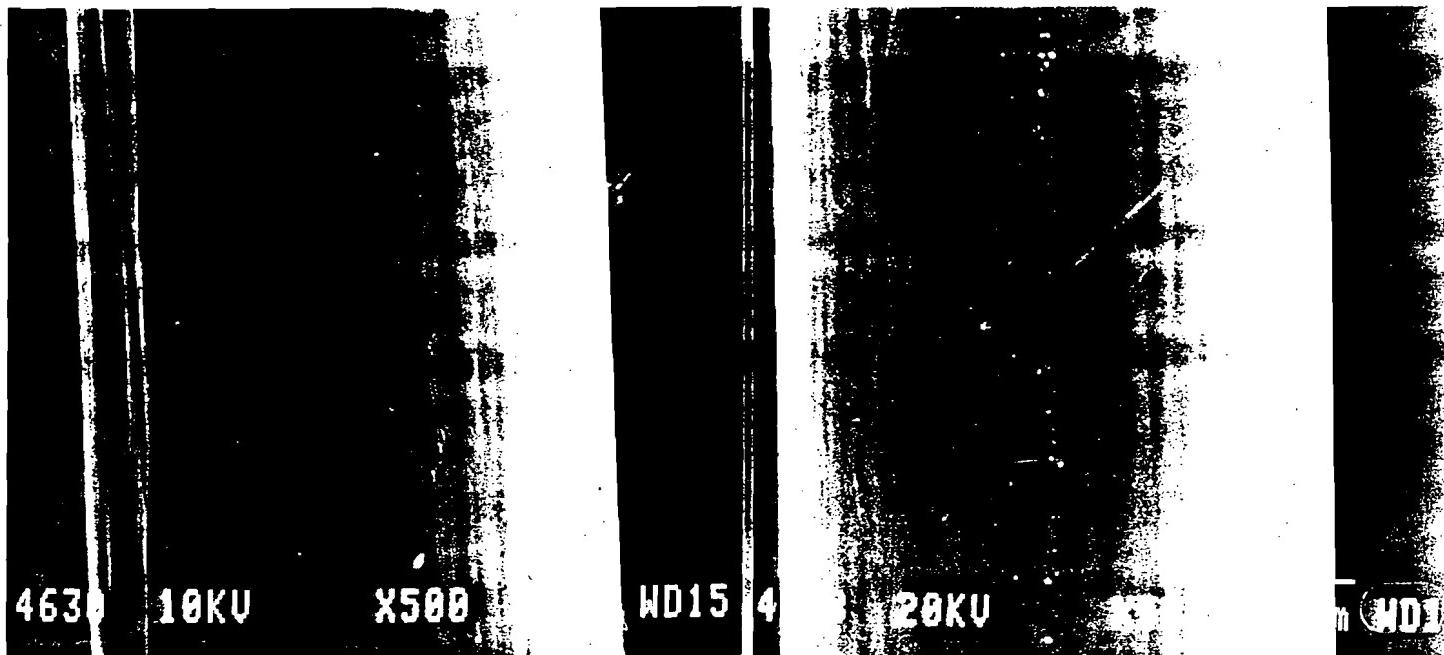
Dog #2018 Site 1



Dog #2018 Site 3

Figure 3

PVDF Explants



Dog #1994 Site 2

Dog #2000 Site 3

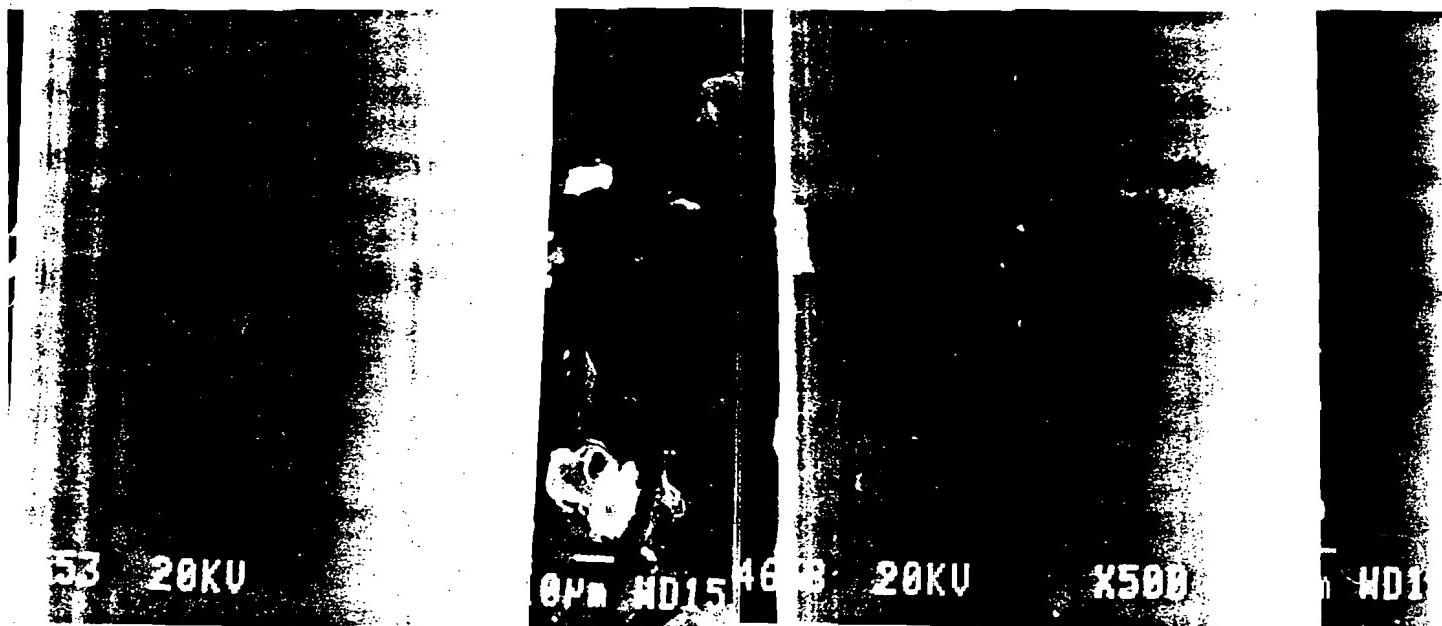


Dog #2006 Site 2

Dog #2006 Site 5

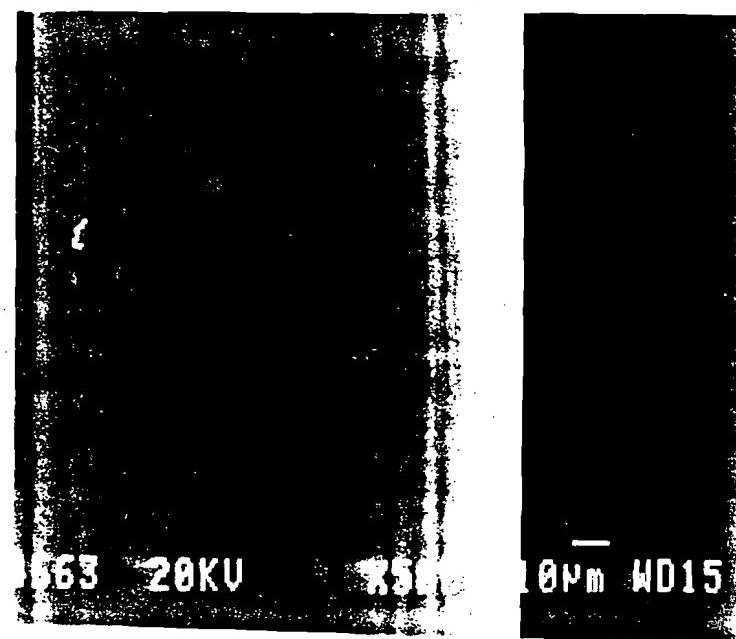
Figure 4

PVDF Explants



Dog #2012 Site 1

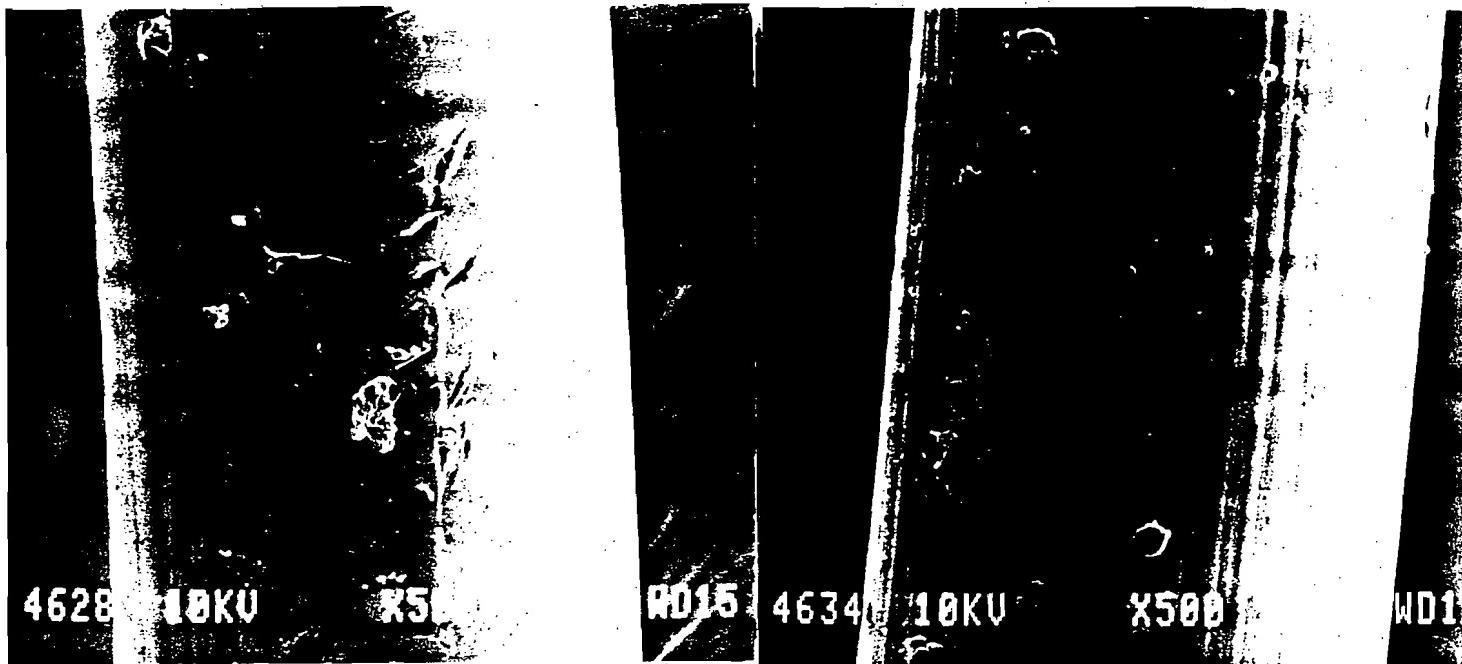
Dog #2012 Site 6



Dog #2018 Site 5

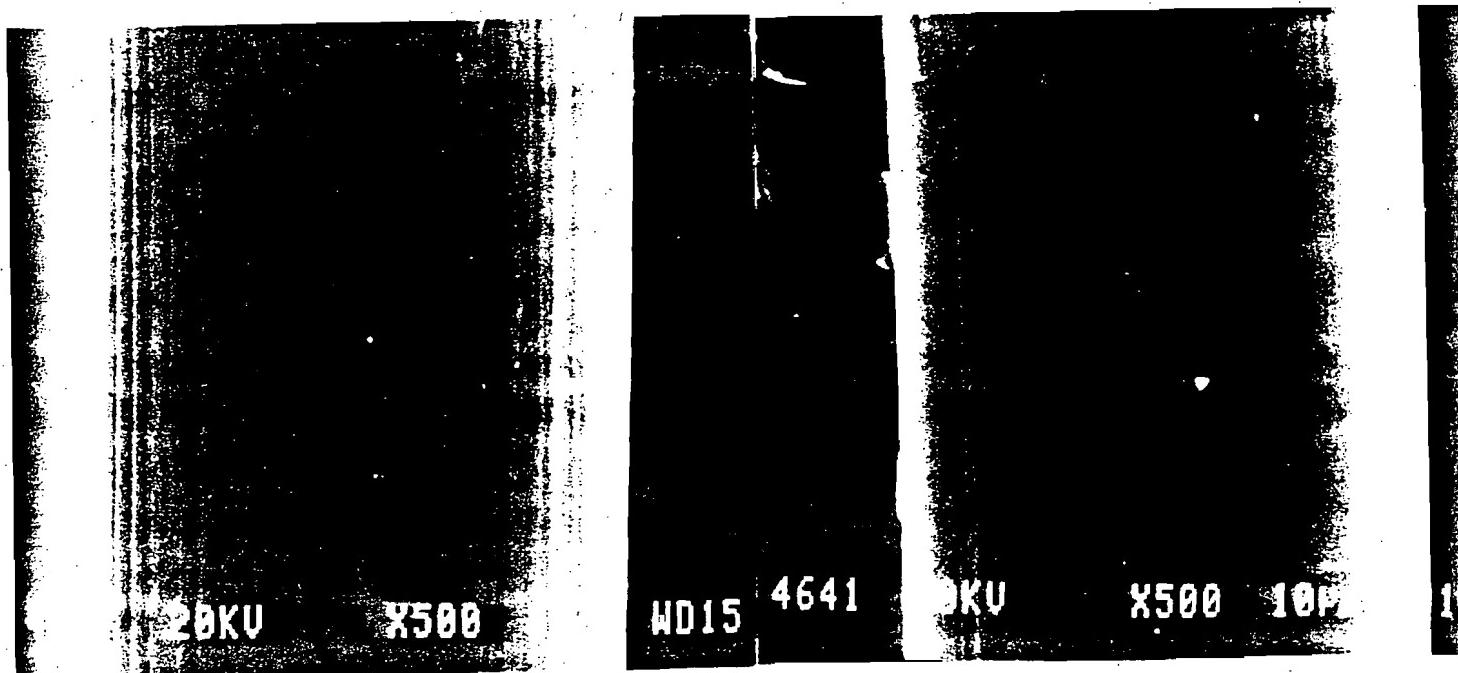
Figure 5

Prolene Explants



Dog #1994 Site 1

Dog #1994 Site 5

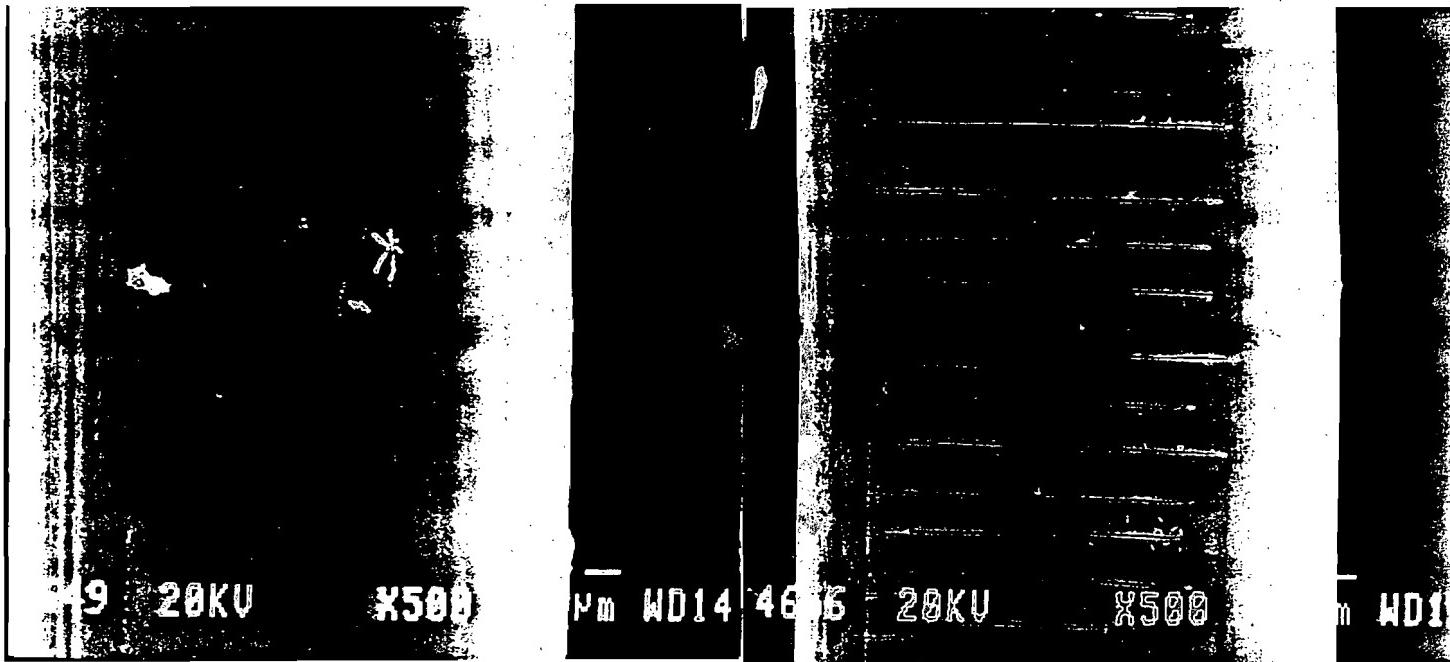


Dog #2000 Site 2

Dog #2000 Site 1

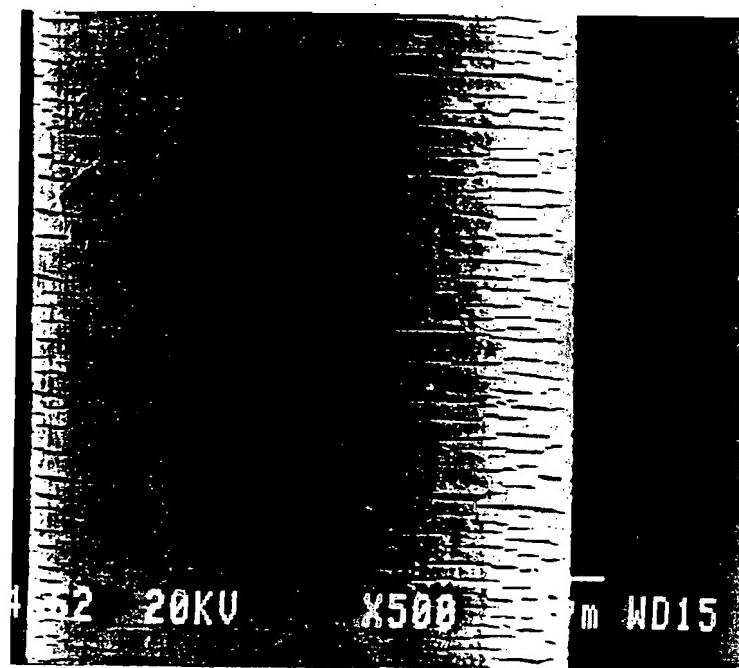
Figure 6

Prolene Explants



Dog #2006 Site 3

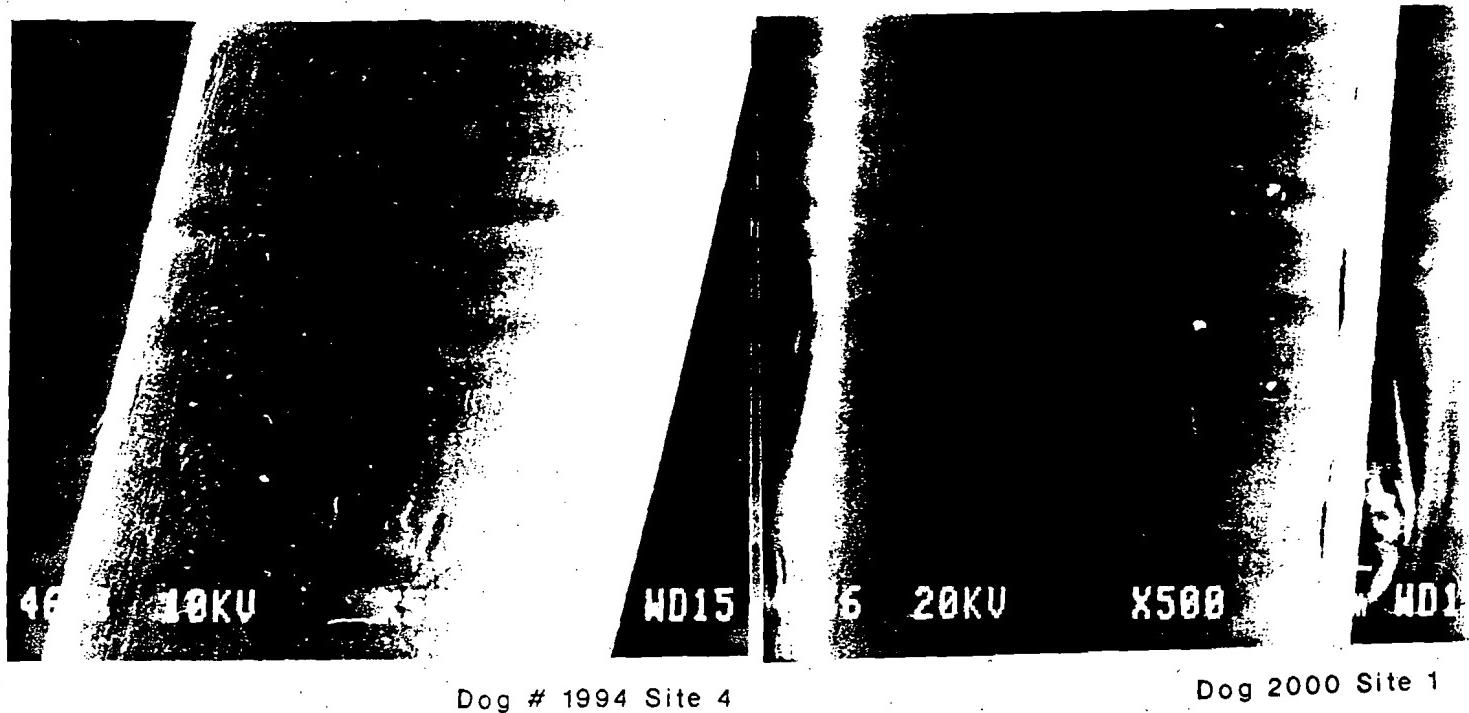
Dog #2012 Site 4



Dog #2018 Site 4

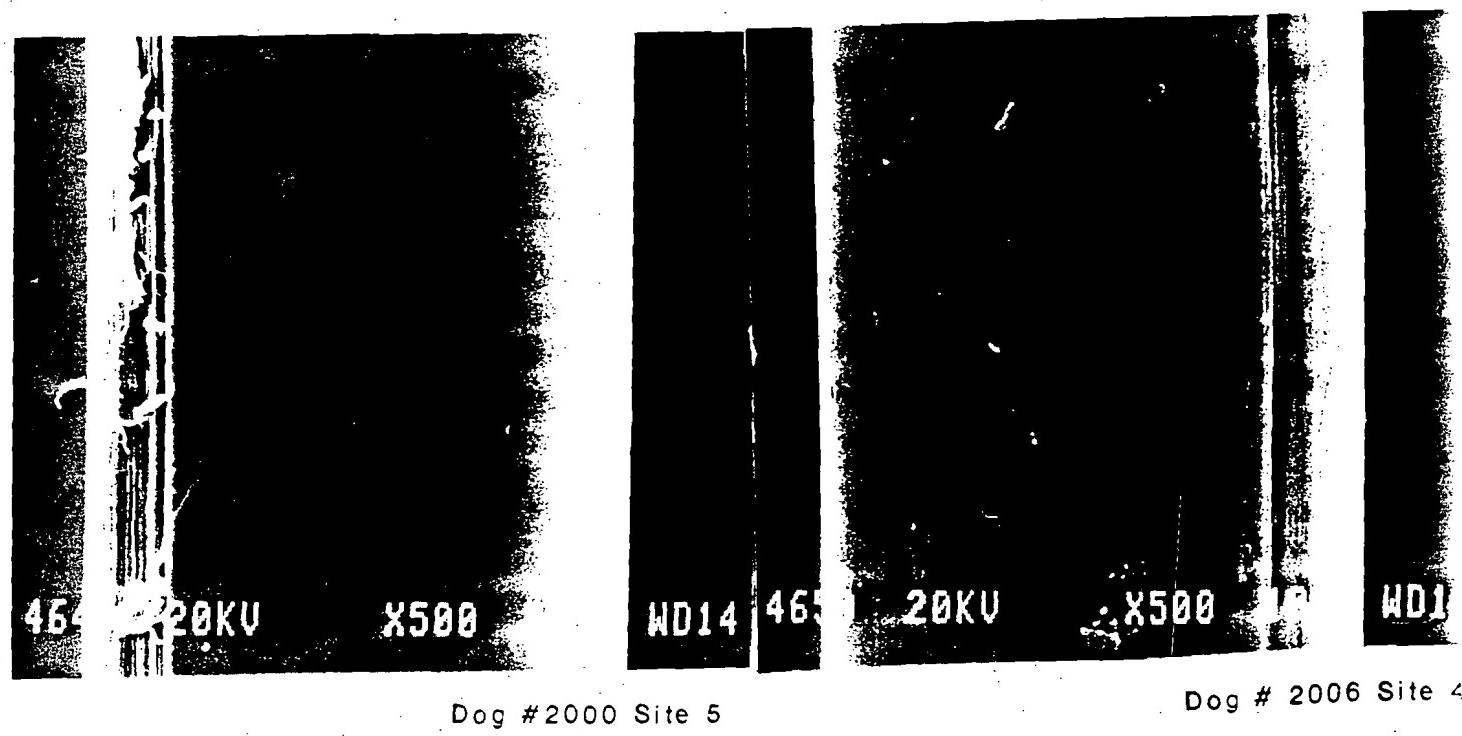
Figure 7

Novafil Explants



Dog # 1994 Site 4

Dog 2000 Site 1



Dog #2000 Site 5

Dog # 2006 Site 4

Figure 8

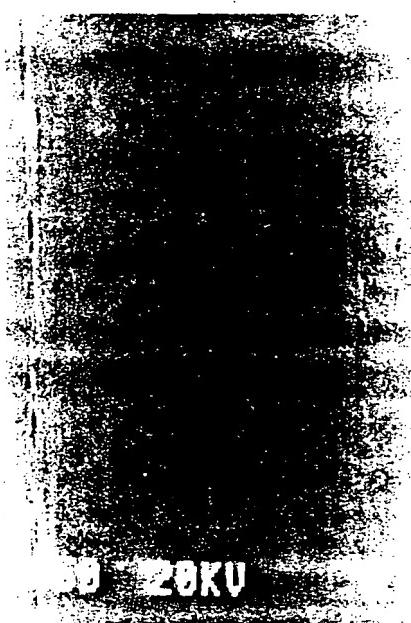
Novafil Explants



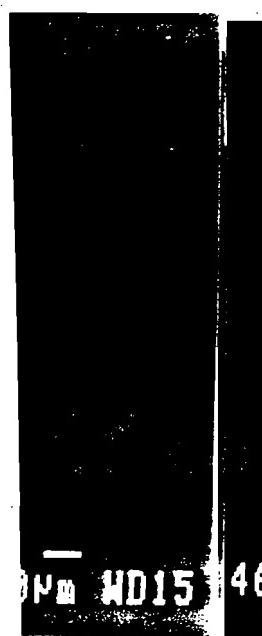
Dog #2006 Site 6



Dog #2012 Site 3



Dog #2018 Site 2



Dog # 2018 Site 6

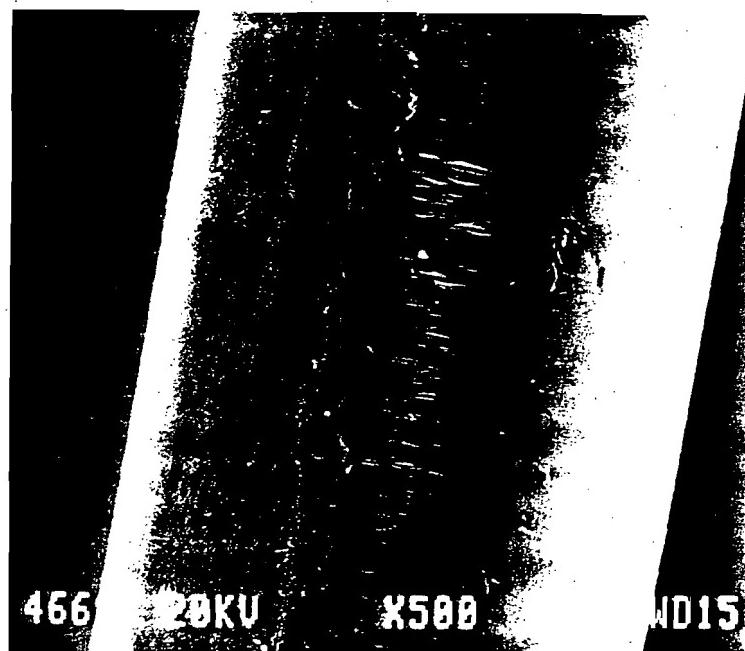


ETH.MESH.11336176

Figure 9

Novafil Explant

45 Days After Explantation



Dog #1994 Site 4